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13281 U.S. PTO

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PTO/SB/50 (08-00)

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REISSUE PATENT APPLICATION TRANSMITTAL


| | | |
|---|--|----------------------|
| Address to: Mail Stop Reissue Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 | Attorney Docket No. | MERCK-2593-R1-C1 |
| | First Named Inventor | Yves BONHOMME et al. |
| | Original Patent Number | 6,303,146 |
| | Original Patent Issue Date (Month/Day/Year) | October 16, 2001 |
| | Express Mail Label No. | |

| | | | |
|--|--|---|--|
| APPLICATION FOR REISSUE OF: (check applicable box) | | | |
| <input checked="" type="checkbox"/> Utility Patent | | <input type="checkbox"/> Design Patent | |
| | | <input type="checkbox"/> Plant Patent | |

| | |
|---|---|
| APPLICATION ELEMENTS (37 CFR 1.173) 1. <input checked="" type="checkbox"/> * Fee Transmittal Form (e.g., PTO/SB/56) (Submit an original, and a duplicate for fee processing) 2. <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. 3. <input checked="" type="checkbox"/> Specification and Claims in a double column copy of patent format (amended, if appropriate) 4. <input checked="" type="checkbox"/> Drawing(s) (proposed amendments, if appropriate) 5. <input checked="" type="checkbox"/> Reissue Oath / Declaration (original or copy) (37 C.F.R. § 1.175)(PTO/SB/51 or 52) 6. Original U.S. Patent currently assigned? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, check applicable box(es)) <input checked="" type="checkbox"/> Written Consent of all Assignees (PTO/SB/53) <input checked="" type="checkbox"/> 37 C.F.R. § 3.73(b) Statement (PTO/SB/96) <input checked="" type="checkbox"/> Power of Attorney | ACCOMPANYING APPLICATION PARTS 7. <input checked="" type="checkbox"/> Statement of status/support for all changes to the claims. See 37 CFR 1.173(c). 8. <input checked="" type="checkbox"/> Original U.S. Patent for surrender <input checked="" type="checkbox"/> Ribbioned Original Patent Grant <input type="checkbox"/> Statement of Loss (PTO/SB/55) 9. <input checked="" type="checkbox"/> Foreign Priority Claim (35 U.S.C. 119) (if applicable) 10. <input checked="" type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations 11. <input type="checkbox"/> English Translation of Reissue Oath/Declaration (if applicable) 12. <input checked="" type="checkbox"/> Preliminary Amendment 13. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized) 14. <input checked="" type="checkbox"/> Other: <u>Ribbioned Original Patent Grant - 6,303,146 has been surrendered to the U.S. Patent and Trademark Office in the parent application Serial No. 10/329,426</u> |
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14. CORRESPONDENCE ADDRESS

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| <input checked="" type="checkbox"/> Customer Number or Bar Code Label | |  | | or <input type="checkbox"/> Correspondence address below | |
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|--------------------------|---|--|----------------|
| NAME (Print/Type) | Anthony J. Zelano | Registration No. (Attorney/Agent) | 27,969 |
| Signature |  | Date | March 25, 2004 |

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450.

17513 U.S. PTO
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032504

REISSUE APPLICATION FEE TRANSMITTAL FORM

Docket Number (Optional)
MERCK-2593-R1-C1

Claims as Filed - Part 1

| Claims in Patent | For | Number Filed in Reissue Application | (3) Number Extra | Small Entity | | Other than a Small Entity | | |
|----------------------------|--|-------------------------------------|------------------|----------------------------------|----------|---------------------------|--------|-----------|
| | | | | Rate | Fee | Rate | Fee | |
| (A) 10 | Total Claims (37 CFR 1.16(j)) Independent Claims (37 CFR 1.16(i)) | (B) 95 | **** 0 | X\$ _____ = X\$ _____ = | | or | X\$18= | 0 |
| (C) 4 | | (D) 9 | * 0 | | | X\$86= | 0 | |
| | | | | | | | | |
| Basic Fee (37 CFR 1.16(h)) | | | | | \$ _____ | | | \$ 770.00 |
| Total Filing Fee | | | | | \$ _____ | OR | | \$ 770.00 |

Claims as Amended - Part 2

| | (1) Claims Remaining After Amendment | | (2) Highest Number Previously Paid For | (3) Extra Claims Present | Small Entity | | Other than a Small Entity | |
|-------------------------------------|--------------------------------------|-------|--|--------------------------|----------------|-----|---------------------------|----------|
| | | | | | Rate | Fee | Rate | Fee |
| Total Claims (37 CFR 1.16(j)) | *** | MINUS | ** | * | X\$ _____ = | or | X\$ _____ = | |
| Independent Claims (37 CFR 1.16(i)) | *** | MINUS | ***** | = | X\$ _____ = | | X\$ _____ = | |
| Total Additional Fee | | | | | \$ _____ | OR | | \$ _____ |

* If the entry in (D) is less than the entry in (C), Write "0" in column 3.

** If the "Highest Number of Total Claims Previously Paid For" is less than 20, Write "20" in this space.

*** After any cancellation of claims

**** If "A" is greater than 20, use (B - A); if "A" is 20 or less, use (B - 20).

***** "Highest Number of Independent Claims Previously Paid For" or Number of Independent Claims in Patent (C).

☐ Applicant claims small entity status. See 27 CFR 1.27.☐ Please charge Deposit Account No. _____ in the amount of _____.
A duplicate copy of this sheet is enclosed.☒ The Commissioner is hereby authorized to charge any additional fees under 37 CFR 1.16 or 1.17 which may be required, or credit any overpayment to Deposit Account No. 13-3402.
A duplicate copy of this sheet is enclosed.☒ A check in the amount of \$ 770.00 to cover the filing / additional fee is enclosed.☐ Payment by credit card. Form PTO-2038 is attached.**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on form PTO-2038.**

March 25, 2004

Date

Signature of Applicant, Attorney or Agent of Record

Anthony J. Zelano, Reg. No. 27,969

Typed or printed name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Yves BONHOMME et al.

Examiner: Susan T. TRAN

Serial No.:

Group Art Unit: 1615

Filed: March 25, 2004

Title: SOLID ORAL DOSAGE FORM COMPRISING A COMBINATION OF
METFORMIN AND GLIBENCLAMIDE

COMMUNICATION

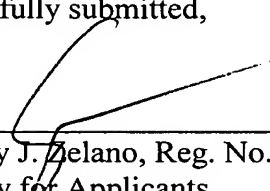
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants are filing this Continuation Reissue Application (Attorney Docket No. MERCK-2593-R1-C1) of Reissue Application Ser. No. 10/329,426 to pursue canceled claims 16, 33, 35-36 and 40 from that application. (The other claims in the application were allowed, except for 41.)

Both the instant application and 10/329,426 seek reissue of U.S. Patent No. 6,303,146.

Respectfully submitted,



Anthony J. Zelano, Reg. No. 27,969
Attorney for Applicants

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Date: March 25, 2004
AJZ:bef

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DOCKET NO.: MERCK-2593-R1-C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :

Yves BONHOMME et al.

Group Art Unit: 1615

Serial No.: 10/329,426

Examiner: Susan T. Tran

Filed: December 27, 2002

U.S. Patent No. 6,303,146

For: SOLID ORAL DOSAGE FORM COMPRISING A COMBINATION OF
METFORMIN AND GLIBENCLAMIDE

SURRENDER OF PATENT

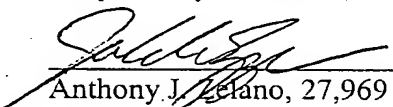
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Attached herewith is the original letters patent of U.S. Patent No. 6,303,146 B1. The patent is hereby surrendered under 37 C.F.R. §1.178 for purposes of re-issuing the patent. It is believed the prosecution to date establishes that all other requirements are met and that the re-issue application is now in condition for allowance. If any issues remain unresolved, the Examiner is kindly invited to contact the undersigned attorneys for applicant.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Anthony J. Zelano, 27,969
John A. Sopp, 33,103
Attorneys for Applicant(s)

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Attorney Docket No.: MERCK-2593 R1

Date: February 17, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re ReissueApplication of:

Yves BONHOMME

Examiner: Unassigned

Serial No.: Unassigned

Group Art Unit: Unassigned

Filed: December 26, 2002

U.S.P. No.: 6,303,146

Title: SOLID ORAL DOSAGE FORM COMPRISING A COMBINATION OF
METFORMIN AND GLIBENCLAMIDE

STATEMENT ACCOMPANYING REISSUE APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a broadening reissue application which is filed well within the two-year anniversary of the issuance of USP 6,303,146 (issue date: October 16, 2001; two-year anniversary: October 16, 2003).

Status/Support for all Changes to Claims

Original claims 1-10 are pending. Original claims 3 and 5 have been amended. New claims 11-41 have been added.

The change to claim 3 is supported by original claim 3 as filed and, e.g., col. 2, lines 50-52. The error resulted from a typographical error when the claim was otherwise amended in prosecution.

Support for the amendment to claim 5 (addition of a reference to parent claim 4) is clearly supported at column 2, lines 55-60. The recitation appearing in claim 5 appears at line 60 of column 2, immediately following the recitations

which appear in parent claim 4 in the immediately preceding paragraph in column 2, at lines 55-59. See also col. 6, lines 12-16. New claim 41 is similarly supported at col. 6, lines 1-8.

As the inventors have explained in the reissue declaration, a general invention was disclosed in the specification filed on July 14, 1999, from which issued U.S.P. 6,303,146, which invention was never previously claimed. This invention is the subject of new claims 11-41.

The general invention is supported in the specification, for example, in the passage at col. 2, lines 41-44, discussed in the Declaration:

The present invention provides in particular a tablet comprising a combination of metformin and glibenclamide, exhibiting a comparable glibenclamide bioavailability to the administered tablets.

Similar support may be found, e.g., in col. 1, lines 54-59:

Appropriate bioavailability implies that 5 mg of glibenclamide formulated into a combination tablet with metformin is absorbed to an acceptably similar extent, and at a comparable rate, to glibenclamide dosed as a single entity formulation of the same strength when dosed concurrently with a single entity formulation of metformin.

See also col. 2, lines 9-18, disclosing that the bioavailability of glibenclamide in the combination tablet "should be as similar as possible to when the relevant doses of the two single entity formulations are co-administered."

All of these exemplary passages refer to a general invention which is disclosed without reference to any particular method to be used to achieve the comparable bioavailability. These provide abundantly clear support for the general invention of the new claims.

Claim 11 is clearly supported by the foregoing passages, particularly that from col. 2, lines 41-44. Claim 12 refers to C_{\max} and AUC as measures of bioavailability. These are used as such throughout the specification. See e.g., col. 4, lines 49-61; col. 5, line 45- col. 6, line 15; and col. 6, lines 53-67. The $\pm 25\%$ ranges for C_{\max} and AUC in Claim 13 are supported at col. 5,

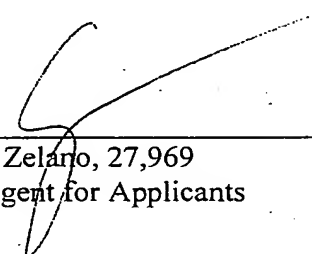
line 65. The values recited in claims 14 and 15 are those in the table at col. 6, lines 55-65. The proviso of claim 16 is clearly supported under the rationale of *In re Johnson*, 558 F. 2d 1008, 194 USPQ 187 (CCPA 1977). See also MPEP § 2173.05(i). The proviso's particle size related aspect is clearly disclosed as part of the invention. See, e.g., col. 2, lines 34-40, among many others. As for dependent claims, these reflect various aspects specifically disclosed in the specification or otherwise supported under relevant case law. For the ratios of claims 17-19, see e.g., col. 1, line 43, col. 2, line 64, and the first row of the table at the top of col. 3. For the unit doses of claims 20 and 21, see, e.g., the table at the top of col. 3. Claim 22 is supported, e.g., at col. 2, line 45 and example 3. Method of treatment claim 31 is supported e.g., at col. 1, lines 7-10 and the original claims.

The sub-ranges recited in claims 23-30 are subsumed by the $\pm 25\%$ ranges recited in claims 13-15 and in the specification at col. 5, line 65, i.e., -25% to +25%. Under Federal Circuit precedent, such subranges have a written description irrespective of whether such subsumed ranges are explicitly recited in the specification. See, e.g., *In re Wertheim*, 541 F.2d. 247, 191 USPQ 90 (CCPA 1976) and *In re Voss*, 547 F.2d. 812, 194 USPQ 267 (CCPA 1977). (Note especially footnote 14 in *Voss* where it is stated: "... description of the range 20-100% (100% being the theoretical upper limit of crystallinity) would necessarily describe the range 50% - 100% crystal content now claimed unless the broad range pertained to a different invention from that involving the narrower range. *In re Wertheim*, supra at 264-65, 191 USPQ at 98.")

Claim 32 is supported as explained, e.g., for claim 1 above, particularly by the passage quoted above from col. 1, lines 54-59. Claim 33 is similarly supported with its proviso being supported for the reasons discussed above for claim 16. Claims 34 and 35 are respectively analogous to claims 32 and 33 with the "increasing" concept being clearly supported, e.g., at col. 2, lines 19-26, col. 4, example, 2, especially the table at col. 4, lines 49-57 and Figures 2 and 3. Claims 37-40 are supported, e.g., at col. 2, lines 61-64.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Anthony J. Zelano, 27,969
Attorney/Agent for Applicants

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Attorney Docket No.: MERCK-2593 R1

Date: December 26, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Yves BONHOMME et al.

Examiner: Susan T. TRAN

Serial No.:

Group Art Unit: 1615

Filed: March 25, 2004

Title: SOLID ORAL DOSAGE FORM COMPRISING A COMBINATION OF
METFORMIN AND GLIBENCLAMIDE

TRANSMITTAL OF CONTINUATION REISSUE APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a continuation reissue application having as parent Reissue Application Serial No. 10/329,426, filed December 27, 2002. That application requested reissue of U. S. Patent No. 6,303,146, originally issued on October 16, 2001. Claims allowed in reissue application 10/329,426 have been canceled from the instant application. Remaining claims 16, 33, 35-36 and 40 are presented for examination. The instant application requests reissue of the claims of U.S. Patent No. 6,303,146 for the same reasons presented in the application of Ser. No. 10/329,426, by the same means of correction.

Submitted with this Transmittal are copies of the following papers, which were also submitted in the parent application, Ser. No. 10/329,426:

- A Declaration/Power of Attorney under 37 C.F.R. §1.63.
- A Reissue Declaration in Accordance with 37 C.F.R. §1.172 and §1.175, including an Offer to Surrender the Patent under 37 C.F.R. §1.178. U.S. Pat. No. 6,303,146 has in fact now been surrendered. See the attached "Surrender of Patent" in the parent.

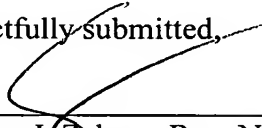
- A Declaration Under 37 C.F.R. §1.132, by Dr. Nicholson.
- The specification of the reissue application in accordance with 37 C.F.R. §1.173.
- A check in payment of the fees for this Reissue Application (\$770.00)
- Copy of a Claim for Foreign Priority Under 35 U.S.C. 119.
- A Written Assent of Assignee under 37 C.F.R. §1.172.
- An IDS and PTO Form 1449. (References not needed in view of 37 C.F.R. §1.98(d))

Also submitted with the Transmittal is:

- a Preliminary Amendment.

If any fees or charges are due, please charge the same to Deposit Account No.13-3402.

Respectfully submitted,



 Anthony J. Zelano, Reg. No. 27,969
 Attorney for Applicants

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Attorney Docket No.: MERCK-2593-R1-C1

Date: March 25, 2004
 AJZ:bcf

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